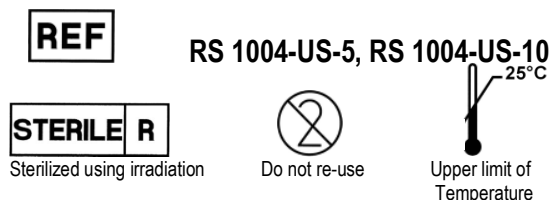


ReSure® Sealant

Instructions for Use



Indication: ReSure® Sealant is indicated for intraoperative management of clear corneal incisions with a wound leak demonstrated by Seidel test, and for prevention of postoperative fluid egress following cataract or intraocular lens placement surgery.

Overview: ReSure Sealant is an *in situ* formed hydrogel that creates a temporary, soft and lubricious sealant to prevent fluid egress following cataract or intraocular lens placement surgery. ReSure hydrogel remains on the corneal surface for up to approximately 7 days, or until re-epithelialization occurs. The cross-linked hydrogel is approximately 89% water at application. ReSure hydrogel softens over time, detaches, and is sloughed off in the tears.

ReSure Sealant consists of one plastic dropper bottle filled with diluent solution, a tray with two mixing wells containing lyophilized deposits of reactants (one blue deposit and one white deposit), and two Applicators.

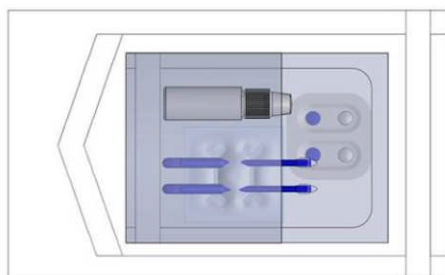


Fig. 1

ReSure Sealant is formed by mixing the Diluent with the dried deposits of reactants. The blue color serves as a visualization aid to ensure proper placement of ReSure Sealant, and diffuses from the hydrogel within hours of application.

Warnings:

- Do not use ReSure Sealant in patients who are allergic to FD&C Blue #1.

Precautions:

- ReSure Sealant is provided sterile. Do not use if packaging or seal has been damaged or opened. Do not re-sterilize.
- The mixing tray, diluent dropper and Applicators should only be used in conjunction with one another.
- The mixing tray, diluent dropper and Applicators are intended for single-use only. Discard opened and unused product.
- Prior to application of ReSure Sealant, ensure incision site is not actively leaking. Remove any standing moisture from the surrounding ocular surface and incision and ensure that the site is dry.
- Use within 30 minutes of removing the mixing tray from foil pouch.

Clinical Trial Summary

A prospective randomized parallel arm controlled multi-center subject-masked study was conducted to establish non-inferiority of ReSure Sealant to suture(s) to prevent incision leakage from clear corneal incisions. The subject population consisted of patients undergoing uncomplicated unilateral clear corneal cataract surgery with phacoemulsification and implantation of a posterior chamber intraocular lens. Four hundred eighty-eight (305 ReSure Sealant and 183 suture) patients were enrolled. The event rate for clear corneal incision leakage within the first 7 days after surgery was 4.1% for subjects treated with ReSure Sealant compared to 34.1% for subjects treated with suture.

These results established both non-inferiority and superiority of ReSure Sealant compared to suture for the mitigation of cataract incision leaks.

Postoperatively all subjects underwent evaluations at approximately 1 hour and 1, 3, 7, 14, 21 and 28 days post procedure. Additionally, subjects were required to complete the Ocular Comfort Index (OCI) once daily for postoperative days 1-7 and weekly at the Day 14, Day 21, and Day 28 visits. The overall incidence of adverse ocular events reported for subjects treated with ReSure Sealant was lower than for subjects treated with suture (22.7% vs. 45.4%).

Adverse events occurred that are related to ReSure Sealant include corneal astigmatism in the acute post-operative period (1.0%), worsening in best corrected visual acuity by greater than two lines (0.3%), eye pain (0.3%), and foreign body in eye (0.3%).

Detailed Preparation

CAUTION: Prior to application of ReSure Sealant, ensure incision site is not actively leaking. Remove any standing moisture from the surrounding conjunctival surface and ensure that the site is dry.

A. Preparing the Tray with Addition of Diluent

1. Using sterile technique, transfer the contents of the Tyvek pouch onto the sterile field.
2. Tear open the foil pouches and carefully remove the Mixing Tray and Diluent Dropper.
3. Remove end cap from the Diluent Dropper and keep cap.
4. Select one channelled well for mixing and add two drops of the Diluent to the blue deposit. Do not add any drops to the white deposit in the same channelled well (Fig. 2).

B. Mixing and Applying ReSure Sealant

NOTE: Mixing and applying ReSure Sealant must be complete in less than 30 seconds.

1. Use the Applicator to thoroughly and rapidly mix the solutions using a back and forth motion (about 5 seconds; Fig. 3).
2. Holding the Applicator handle with the side edge of the foam tip facing down, gently dip the foam tip into the solution, picking up the material (Fig. 4).
3. Apply ReSure Sealant over the entire length, width and edges of the incision, ensuring full coverage of the margins (Fig. 5).



Fig. 2

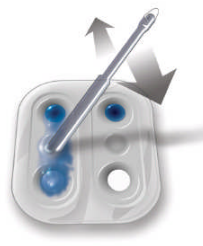


Fig. 3

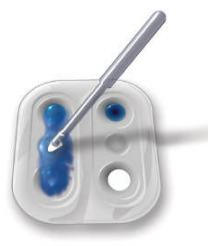


Fig. 4

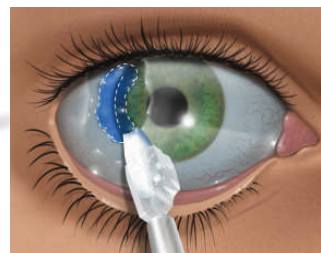


Fig. 5

NOTE: Stop manipulation of the Applicator if liquid material stranding is observed. If application to the incision site was not completed prior to stranding, prepare the second channelled well and reapply.

NOTE: If full coverage is not obtained with one application, a second channelled well is provided. A second ReSure Sealant device may be opened to achieve full coverage.

CAUTION: Each Applicator is intended for single-use only. If a second application is required, use a new Applicator.

4. Delay introduction of any ophthalmic drops to the ocular surface for approximately 30 seconds after application of ReSure Sealant to ensure polymerization of the material and complete adherence and coverage of the target area.

NOTE: ReSure Sealant may be removed carefully with forceps if necessary.



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